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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,471	07/17/2001	James Martin Lenhard	PU3610USW	3999

23347 7590 09/05/2003

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,471	LENHARD, JAMES MARTIN	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 26-36, 41-48, 55, 56, 58-63 and 71-181 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-4, 26-36, 41-48, 55, 56, 58-63, and 71-181 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Unity of Invention

35 U.S.C. § 371

1. This application was filed under 35 U.S.C. § 371 and is subject to unity of invention practice pursuant to 35 U.S.C. § 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive
5 concept under PCT Rule 13.1. In accordance with 37 C.F.R. § 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- 10 a. Group I, claim(s) 1, 2, and 71-90, drawn to methods of screening retroviral therapeutic agents (RTAs) for their capacity to affect lipodystrophy by measuring the inhibition of adipogenesis.
- 15 b. Group II, claim(s) 3 and 91-111, drawn to methods of screening RTAs for their capacity to affect lipodystrophy by measuring net lipogenesis.
- 20 c. Group III, claim(s) 4 and 112-132, drawn to methods of screening RTAs for their capacity to affect lipodystrophy by measuring net lipolysis.
- 25 d. Group IV, claim(s) 26-30, drawn to methods of screening RTAs for their capacity to affect lipodystrophy by monitoring PPAR γ :RXR-regulated gene expression.
- 30 e. Group V, claim(s) 31-34, 48 and 153-158, drawn to methods of screening protease inhibitors (PIs) for their capacity to affect lipodystrophy by monitoring retinoid-activated gene expression.
- f. Group VI, claim(s) 35 and 133-136, drawn to a method for identifying compounds that affect fat metabolism employing a receptor ligand displacement binding assay.
- 35 g. Group VII, claim(s) 36 and 137-140, drawn to a method for identifying compounds that affect fat metabolism employing a receptor ligand binding assay.

- h. Group VIII, claim(s) 41, 42, and 141-144, drawn to methods of screening RTAs for their capacity to affect lipodystrophy by monitoring serum lipid levels.
- 5 i. Group IX, claim(s) 43-46 and 145-148, drawn to methods of screening RTAs for their capacity to affect lipodystrophy by monitoring net fat deposition.
- 10 j. Group X, claim(s) 47 and 149-152, drawn to methods of screening RTAs for their capacity to affect lipodystrophy by monitoring blood urea nitrogen levels.
- 15 k. Group XI, claim(s) 55, 56, 159, and 160, drawn toward transgenic mice expressing a transgene that confers sensitivity toward RTAs.
- 20 l. Group XII, claim(s) 58-61 and 161-174, drawn to transgenic murine screening methods to identify RTA-induced lipodystrophy modulators.
- m. Group XIII, claim(s) 62, 63, and 175-181, drawn to patient classification protocols.

25 The inventions listed as Groups I-XIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature. The aforementioned groups are directed toward disparate products and methodologies that employ different scientific reagents and protocols and accomplish different scientific objectives.

30 Moreover, the claimed invention fails to make a contribution over the prior art (i.e., see the ISA Chapter I search report). Thus, each of the identified groups is clearly directed toward and independent and distinct invention.

35 2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. Applicant is also advised that the claims should be amended, where necessary, to reflect the restriction requirement and election.

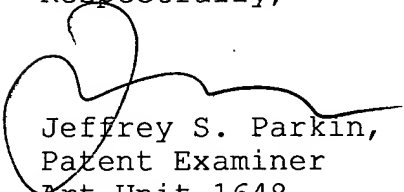
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Correspondence

3. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future
5 correspondence should be directed to **art unit 1648**.

4. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be
10 directed toward the following Group 1600 fax number: (703) 872-9306. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday
15 from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the
20 status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

04 September, 2003